K020944

VORTEX 510(k) Submission
510(k) Summary

MAY 0 9 2002

Submitter Information

Name:	PARI Innovative Manufacturers, Inc.
Address:	13800 Hull Street Road Midlothian, Virginia 23112
Phone Number:	804-639-7235
FAX Number:	804-639-7244
Contact Name:	Lawrence Weinstein
Date Prepared:	February 14, 2002

Device Name

Common Name:	Holding Chamber/Spacer
Proprietary Name:	Vortex®
Classification Name:	Nebulizer (Direct Patient Interface)

Legally Marketed Predicate Device

Aerochamber
Monaghan Medical (and/or Trudell Medical)
Plattsburgh, NY

K992917; K930574; K900576; K900557; K884803; K872037; K822437

Device Description

Vortex is a new spacer/holding chamber designed to assist patients using metered dose inhalers (MDI) for aerosolized drug delivery. Vortex may provide enhanced drug delivery, ease of use and ability to clean/disinfect the device.

Vortex is a reusable device consisting of an aluminum cylinder with an elastomeric fitting on one end to accept metered dose inhalers and a valved mouthpiece on the other end to interface with the patient. The elastomeric fitting may be removed for cleaning and/or replacement.

Vortex will be available as a stand-alone item and will also be available packaged with a mask.

Intended Use

Vortex is indicated for use as a spacer/valved holding chamber for use in delivery of aerosol medication with metered dose inhalers.

Technological Characteristics Compared to Predicate Device

Vortex and Aerochamber are both valved holding chambers used to aid in the delivery of MDI medications. Both products include a cylindrical chamber to allow the MDI drug plume to expand prior to inhalation by the patient. In addition, both make use of inhalation and exhalation valves to reduce coordination related problems with MDI actuation.

Vortex and Aerochamber make use of thermoplastic components and elastomeric valves and MDI adapters. However, Vortex makes use of a non-electrostatic (anodized aluminum) cylinder to reduce the likelihood of drug deposition on the cylinder.

Non-clinical Test Summary

Testing to compare Vortex to Aerochamber was conducted. Characteristics evaluated include:

- Drug delivery (per FDA guidance): Respirable drug delivered through Vortex is comparable to or greater than Aerochamber.
- Fit with MDI elbows: Vortex fit all MDI elbows evaluated.

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- Inhalation and exhalation resistance: Inhalation and exhalation resistance for Vortex is comparable to or less than Aerochamber. All results are less than 250 pascal at 30 lpm flow.

Clinical Performance Summary

Clinical testing was not completed/is not required to show substantial equivalence.

Conclusions from Testing

Vortex performance is comparable to Aerochamber for all items tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

Pari Innovative Manufacturers, Inc..
c/o Robert Mosenkis
CITECH
5200 Butler Pike
Plymouth Metting, PA 19462

Re: K020944
Vortex Valved Holding Chamber
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: April 24, 2002
Received: April 25, 2002

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of May 9, 2002 regarding the indications for use of your device. Our letter incorrectly limited your device to use in military environments.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your

device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

VORTEX 510(k) Submission
Intended Use

510(k) Number (if known): K020944

Device Name: Vortex™ Valved Holding Chamber

Indications for Use:

Vortex is indicated for use as a spacer/valved holding chamber for use in delivery of aerosol medication with metered dose inhalers.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020944